



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2014-0278; FRL-9911-16]

Registration Review Proposed and Proposed Interim Decisions; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of EPA's proposed registration review decisions and opens a public comment period on the proposed and proposed interim decisions. Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, that the pesticide can perform its intended function without unreasonable adverse effects on human health or the environment. Through this program, EPA is ensuring that each pesticide's registration is based on current scientific and other knowledge, including its effects on human health and the environment. This document also announces the registration review case closure for the pesticide amitrole (case 0095) and the availability of the amitrole case closure document. The cancellation of all amitrole product registrations became effective on April 11, 2014. This case closure for amitrole is being announced herein with no comment period.

DATES: Comments must be received on or before [*INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER*].

ADDRESSES: Submit your comments, identified by the docket identification (ID) number for the specific pesticide of interest provided in the table in Unit II.A., by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For pesticide specific information, contact:* The Chemical Review Manager for the pesticide of interest identified in the table in Unit II.A.

For general information on the registration review program, contact: Richard Dumas, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs,

Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC
20460-0001; telephone number: (703) 308-8015; email address:

dumas.richard@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, farm worker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the Chemical Review Manager for the pesticide of interest identified in the table in Unit II.A.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in

the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- vi. Provide specific examples to illustrate your concerns and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What Action is the Agency Taking?

Pursuant to 40 CFR 155.58, this notice announces the availability of EPA's proposed and proposed interim registration review decisions for the pesticides shown in the following table, and opens a 60-day public comment period on the proposed and proposed interim decisions.

Ancymidol (Proposed Interim Decision)

The registration review docket for ancymidol (EPA-HQ-OPP-2011-0482) opened in June 2011. Ancymidol is a plant growth regulator registered for treating container-grown herbaceous plants, ornamental woody shrubs, and bedding plants grown in greenhouses and in outdoor plant-bedding areas. It is also registered for use as a seed treatment for ornamental plants, and treated seeds are used to start plants. Use of ancymidol is limited to nursery grown ornamentals. There are no food, feed, or residential uses registered for ancymidol. No pesticide tolerances have been established. EPA conducted a qualitative assessment for both human health and ecological risks. No risks of concern were identified in the human health risk assessment. The ecological risk assessment indicated that there was no reasonable expectation for any registered use of ancymidol to cause direct or indirect adverse effects to threatened and endangered species. A "no effect" determination was made for all federally listed species and designated critical habitat. Ancymidol has not been evaluated under the Endocrine Disruptor Screening Program (EDSP). Therefore, the Agency's final registration review decision is dependent upon the result of the evaluation of potential endocrine disruptor

risk. Pending the outcome of this action, EPA is planning to issue an interim registration review decision for ancymidol.

DEET (Combined Work Plan and Proposed Interim Decision)

The registration review docket for DEET (N,N-diethyl-meta-toulamide) is opening (EPA-HQ-OPP-2012-0162) for public comment on a combined Work Plan and Proposed Interim Registration Review Decision. DEET is a broad-spectrum insect repellent registered for use against biting flies, biting midges, black flies, chiggers, deer flies, fleas, gnats, horse flies, mosquitoes, no-see-ums, sand flies, stable flies, and ticks. It is currently registered for non-food uses and residential uses. It can be directly used on clothing, applied to the skin, and used on horses. EPA conducted a qualitative assessment for both human health and environmental fate and ecological risks. No risks of concern were identified. The ecological risk assessment made a “no effect” determination for federally listed species and designated critical habitat. DEET has not been evaluated under the EDSP. Therefore, the Agency’s final registration review decision is dependent upon the result of the evaluation of potential endocrine disruptor risk. Pending the outcome of this action, EPA is planning to issue an interim registration review decision for DEET.

Denatonium Saccharide (Proposed Interim Decision)

The registration review docket for denatonium saccharide (EPA-HQ-OPP-2008-0441) opened in June 2008. Denatonium saccharide is a bittering agent in squirrel, vole, dog, and cat repellents used on outdoor surfaces and structures such as trees, fences, poles, decks, planters, siding, garbage cans, furniture, seeds, and bulbs. EPA conducted a qualitative human health risk assessment and did not identify any risks of concern. The

ecological risk assessment identified potential risks for birds and listed mammals. However, due to the number of conservative assumptions included in the assessment, the Agency is not proposing mitigation changes at this time. The risk assessment for denatonium saccharide did not come to a conclusion of “no effect” to listed species. Therefore, consultation with the U.S. Fish and Wildlife Service (USFWS) on the potential risk of denatonium saccharide to listed species will be necessary. Denatonium saccharide has not been evaluated under the EDSP. Therefore, the Agency’s final registration review decision is dependent upon the result of Section 7 Endangered Species consultation with the USFWS and the evaluation of potential endocrine disruptor risk. Pending the outcome of these actions, EPA is planning to issue an interim registration review decision for denatonium saccharide.

Diocetyl Sodium Sulfosuccinate (Proposed Decision)

The registration review docket for DSS (EPA-HQ-OPP-2010-1006) opened in December 2010. DSS is registered as an insecticide and miticide in pet shampoos and spray products in combination with Undecylenic Acid (UDA). As a pesticidal active ingredient, there are no food uses and, thus, no tolerances are established. DSS is used as an active ingredient in over the counter stool-softener and laxative products for infants, children, and adults; it is also used in pharmaceutical, cosmetic, and food products. EPA has conducted a qualitative assessment for both human health and ecological risks, including listed species for DSS. The human health risk assessment did not identify any risks of concern for DSS. The ecological risk assessment made a “no effect” determination for federally listed species and designated critical habitat. Pursuant to FFDCA Section 408(p)(4), EPA has exempted DSS from the requirements of the EDSP

in an Administrative Order entitled *Exemption of Dioctyl Sodium Sulfosuccinate (DSS) and Undecylenic Acid (UDA) from the Requirements of the Endocrine Disruptor Screening Program* which is available in the registration review docket.

Gas Cartridges; Inorganic Nitrate – Nitrite, Carbon and Carbon Dioxide, and Sulfur (Proposed Interim Decision)

Potassium and sodium nitrate, carbon and carbon dioxide, and sulfur are ingredients in fumigant gas cartridge products, which are available in small and large sizes. Both sizes are registered to control burrowing mammals, but only the large gas cartridge is registered to also control coyotes, red foxes and skunks. Gas cartridges are registered for outdoor use only. To use the products, the user lights the fuse, places the cartridge in the burrow or den and seals the entrance. Animals within the burrow or den are asphyxiated by the release of carbon dioxide and toxic gases.

The Agency relied on a previous human health risk assessment in making its registration review decisions and determined that no human health risks of concern exist for these compounds. The Agency conducted a new ecological risk assessment for the gas cartridges for registration review. The risk assessment did find the potential for adverse effects to a number of endangered species from gas cartridge use. EPA developed mitigation to address the risk to a number of the endangered species. In most cases, the mitigation involves the use of Endangered Species Protection Bulletins. Because the gas cartridges contain the three compounds, these Bulletins are available for comment in the Inorganic Nitrate – Nitrite, Carbon and Carbon Dioxide, and Sulfur Registration Review dockets (EPA-HQ-OPP-2007-1118, EPA-HQ-OPP-2007-0705, and EPA-HQ-OPP-2008-0176, respectively). Although implementation of these Bulletins

will address risk to some endangered species from gas cartridge use, risk to a number of other endangered species remains. Additionally, potassium and sodium nitrate, carbon and carbon dioxide, and sulfur have not been evaluated under the EDSP. Therefore, the Agency's final registration review decisions are dependent upon the result of Section 7 Endangered Species consultation with the USFWS and the evaluation of potential endocrine disruptor risk. Pending the outcome of these actions, EPA is planning to issue interim registration review decisions for sodium and potassium nitrate, carbon and carbon dioxide, and sulfur.

Metofluthrin (Proposed Interim Decision)

The registration review docket for metofluthrin (EPA-HQ-OPP-2012-0105) opened in June 2013. Metofluthrin is a Type 1 synthetic pyrethroid insect repellent and insecticide with products registered for use in residential and commercial areas, including barns, patios, porches, campgrounds, stables and kennels to repel adult mosquitoes and kill bed bugs. The products registered for outdoor use are an impregnated paper repellent strip, a battery-operated personal outdoor insect repellent fan, an impregnated fiberglass ring heated by a candle, and battery-operated automated mister. The registered indoor use is a soluble concentrate used as a spray to kill bedbugs. There are no registered food/feed uses for metofluthrin. No pesticide tolerances have been established. EPA conducted a human health risk assessment and an ecological risk assessment. No risks of concern were identified in the human health risk assessment. The ecological risk assessment indicated that there was no reasonable expectation for any registered use of metofluthrin to cause direct or indirect adverse effects to threatened and endangered species. A "no effect" determination was made for all federally listed species and designated critical

habitat. Metofluthrin has not been evaluated under the EDSP. Therefore, the Agency's final registration review decision is dependent upon the result of the evaluation of potential endocrine disruptor risk. Pending the outcome of this action, EPA is planning to issue an interim registration review decision for metofluthrin.

Polybutene Resins (Proposed Decision)

The registration review docket for polybutene resins (EPA-HQ-OPP-2009-0649) opened in June 2010. Polybutene is a sticky polymer registered for use as a bird and small mammal repellent. It is used to prevent house sparrows, pigeons, and starlings from roosting inside and outside of buildings, as well as to prevent beavers from attacking trees and shrubs. There are no food/feed uses and, it is exempt from a tolerance requirement when used as a sticker agent in packaging of insect control products used on food crops. Polybutene is approved by the U.S. Food and Drug Administration (FDA) as an indirect food additive and is used as an ingredient in cosmetic products that are applied directly to the skin such as sun block or moisturizer, and that may be incidentally ingested, such as lipstick. EPA conducted a qualitative assessment for both human health and environmental fate and ecological risks. No risks of concern were identified in the human health risk assessment. The ecological risk assessment indicated that there was no reasonable expectation for any registered use of polybutene to cause direct or indirect adverse effects to threatened and endangered species. A "no effect" determination was made for all federally listed species and designated critical habitat. Pursuant to FFDCA Section 408(p)(4), EPA has exempted polybutene from the requirements of the EDSP in an Administrative Order (AO) entitled *Exemption of Polybutene from the Requirements*

of the Endocrine Disruptor Screening Program. The AO is available in the registration review docket.

Sulfur (Proposed Interim Decision)

The registration review docket for sulfur (EPA-HQ-OPP-2008-0176) opened in March 2008. Sulfur is used as an insecticide and fungicide on a wide range of field and greenhouse-grown food and feed crops, livestock, livestock quarters, and indoor and outdoor residential sites. Sulfur is also registered for use in gas cartridge products, along with inorganic nitrate/nitrite, carbon, and carbon dioxide. EPA has conducted a qualitative assessment for both human health and ecological risks, including listed species for sulfur. Details of the assessment for the gas cartridge use are summarized under the gas cartridge heading in this unit. For uses of sulfur other than gas cartridges, the Agency is making a “no effect” determination for all listed aquatic species, and a “no effect” determination for direct effects to listed terrestrial vertebrates that do not rely on insects as a primary food source. However, at this time, the Agency is not able to make an endangered species determination on terrestrial invertebrates, terrestrial plants, or indirect effects to terrestrial vertebrates with insects as a primary food source. Sulfur has not been evaluated under the EDSP. Therefore, the Agency’s final registration review decision is dependent upon the result of Section 7 Endangered Species consultation with the USFWS and the evaluation of potential endocrine disruptor risk. Pending the outcome of these actions, EPA is planning to issue an interim registration review decision for sulfur.

Undecylenic Acid (Proposed Decision)

The registration review docket for UDA (EPA-HQ-OPP-2011-0910) opened in December 2011. UDA is registered as an insecticide and miticide in pet shampoos and spray products in combination with dioctyl sodium sulfosuccinate (DSS). As a pesticidal active ingredient, there are no food uses and, thus, no tolerances are established. UDA is approved by the FDA as an active ingredient in over the counter anti-fungal products, and it is also used as a flavoring agent. EPA has conducted a qualitative assessment for both human health and ecological risks, including listed species for UDA. The human health risk assessment did not identify any risks of concern for UDA. The ecological risk assessment made a “no effect” determination for federally listed species and designated critical habitat. Pursuant to FFDCA Section 408(p)(4), EPA has exempted UDA from the requirements of the EDSP in an AO entitled *Exemption of Dioctyl Sodium Sulfosuccinate (DSS) and Undecylenic Acid (UDA) from the Requirements of the Endocrine Disruptor Screening Program* which is available in the registration review docket.

This notice also announces the registration review case closure for the pesticide amitrole (case 0095) and the availability of the amitrole case closure document. The Notice of Receipt of a Request to Voluntarily Cancel Certain Pesticide Registrations was issued in the **Federal Register** of August 28, 2013 (78 FR 53141)(FRL-9396-4), and no substantive public comments were received during the 180-day comment period that impacted the Agency's decision to grant the cancellation request. In the **Federal Register** of April 11, 2014 (79 FR 20199) (FRL-9908-31), the Agency published the Cancellation Order for all amitrole product registrations. Due to the cancellation of all registered amitrole products in the United States, the Agency closed the registration review case for

amitrole, pursuant to 40 CFR 155.42(c). In addition to the registration review case closure document, the registration review docket (EPA-HQ-OPP-2011-0105) for amitrole, also includes other relevant documents related to the registration review of this case. This action is not open for public comment.

Table--Registration Review Proposed and Proposed Interim Final Decisions

Registration Review Case Name and Number	Pesticide Docket ID Number	Chemical Review Manager, Telephone Number, Email Address
Ancymidol (Case #3017)	EPA-HQ-OPP-2011-0482	Christina Scheltema 703-308-2201 scheltema.christina@epa.gov
Carbon and Carbon Dioxide (Case #4019)	EPA-HQ-OPP-2007-0705	Carissa Cyran 703-347-8781 cyran.carissa@epa.gov
DEET (N,N-diethyl-meta-toulamide) (Case #0002)	EPA-HQ-OPP-2012-0162	Susan Bartow 703-603-0065 bartow.susan@epa.gov
Denatonium Saccharide (Case #7625)	EPA-HQ-OPP-2008-0441	Cathryn Britton 703-308-0136 britton.cathryn@epa.gov
Dioctyl Sodium Sulfosuccinate (Case #4029)	EPA-HQ-OPP-2010-1006	Garland Waleko 703-308-8049 waleko.garland@epa.gov
Inorganic Nitrate – Nitrite (Case #4052)	EPA-HQ-OPP-2007-1118	Eric Miederhoff 703-347-8028 miederhoff.eric@epa.gov

Metofluthrin (Case 7445)	EPA-HQ-OPP-2012-0105	Veronica Dutch 703-308-8585 dutch.veronica@epa.gov
Polybutene Resins (Case #4076)	EPA-HQ-OPP-2009-0649	Joel Wolf 703-347-0228 wolf.joel@epa.gov
Sulfur (Case #0031)	EPA-HQ-OPP-2008-0176	Tanja Crk 703-308-8202 crk.tanja@epa.com
Undecylenic Acid (Case #4095)	EPA-HQ-OPP-2011-0910	Garland Waleko 703-308-8049 waleko.garland@epa.gov

The registration review docket for a pesticide includes earlier documents related to the registration review of the case. For example, the review opened with a Summary Document, containing a Preliminary Work Plan, for public comment. A Final Work Plan was placed in the docket following public comment on the initial docket.

The documents in the dockets describe EPA's rationales for conducting additional risk assessments for the registration review of the pesticides included in the table in Unit II.A., as well as the Agency's subsequent risk findings and consideration of possible risk mitigation measures. These proposed and proposed interim registration review decisions are supported by the rationales included in those documents.

Following public comment, the Agency will issue final registration review decisions or interim registration review decisions for products containing the pesticides listed in the table in Unit II.A.

The registration review program is being conducted under congressionally mandated time frames, and EPA recognizes the need both to make timely decisions and to involve the public. Section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) required EPA to establish by regulation procedures for reviewing pesticide registrations, originally with a goal of reviewing each pesticide's registration every 15 years to ensure that a pesticide continues to meet the FIFRA standard for registration. The Agency's final rule to implement this program was issued in August 2006 and became effective in October 2006, and appears at 40 CFR part 155, subpart C. The Pesticide Registration Improvement Act of 2003 (PRIA) was amended and extended in September 2007. FIFRA, as amended by PRIA in 2007, requires EPA to complete registration review decisions by October 1, 2022, for all pesticides registered as of October 1, 2007.

The registration review final rule at 40 CFR 155.58(a) provides for a minimum 60-day public comment period on all proposed registration review decisions. This comment period is intended to provide an opportunity for public input and a mechanism for initiating any necessary amendments to the proposed decision. All comments should be submitted using the methods in **ADDRESSES**, and must be received by EPA on or before the closing date. These comments will become part of the docket for the pesticides included in the table in Unit II.A. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments.

The Agency will carefully consider all comments received by the closing date and will provide a "Response to Comments Memorandum" in the docket. The final

registration review decision will explain the effect that any comments had on the decision and provide the Agency's response to significant comments.

Background on the registration review program is provided at:

http://www.epa.gov/oppsrrd1/registration_review. Links to earlier documents related to the registration review of these pesticides are provided at:

http://www.epa.gov/oppsrrd1/registration_review/reg_review_status.htm.

B. What is the Agency's Authority for Taking this Action?

Section 3(g) of FIFRA and 40 CFR part 155, subpart C, provide authority for this action.

List of Subjects

Environmental protection, Administrative practice and procedure, Pesticides and pests, Ancyridol, Amitrole, Carbon and Carbon Dioxide, DEET, Denatonium Saccharide, Dioctyl Sodium Sulfosuccinate, Inorganic Nitrate – Nitrite, Metofluthrin, Polybutene Resins, Sulfur, and Undecylenic Acid.

Dated: May 28, 2014.

Richard P. Keigwin, Jr.,

Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.

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